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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,888

07/17/2003

Robert Gurny

4-20437D

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08/04/2006

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/623,888	Applicant(s) GURNY ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment dated 6-15-06 is acknowledged.

Claims included in the prosecution are 1, 32 and 34-37.

In view of the amendments to the claims, the 112, second paragraph rejection is withdrawn.

### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 4-6 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allemann et al (international Journal of Pharmacology, 1992) of record in combination with Kawata (4,343,789) or Igari (5,482,706) or Kantor (4,895,725) by themselves or in combination.

Allemann et al disclose a process of preparation of polymeric nanodispersions containing water-soluble polymer (polyvinyl alcohol) and Eudragit S (anionic polymer which is soluble from pH 7 upwards) or ethyl acetate (abstract and page 248). What is lacking in Allemann is the teaching of the use of these nanospheres for encapsulating water insoluble drugs. However, on page 253 Allemann teaches that these nanospheres are for sustained release dosage forms and therefore, it would have been prima facie obvious to one of ordinary skill in the art to use Allemann's nanosphere dispersions for the water insoluble drugs with a reasonable expectation of success.

As pointed out in the earlier action, Kawata et al disclose fine powders of active

Art Unit: 1615

agents of low solubility coated with various copolymers of methacrylic acid and methacrylic esters or hydroxypropylmethyl cellulose phthalates. The fine particles are mixed with additives and filled in capsules for oral delivery. The particles can be lyophilized. (Abstract, col. 2, lines 13-44, col. 5, lines 10-20, Examples and claims).

Igari teaches that drugs can be delivered orally using enteric-coated nanocapsule suspensions (col. 11, lines 59-61).

Kantor teaches that lipophilic compounds such as fish oils can be delivered orally by using enterically coated capsules. The lower limit of the capsules is 100 nm. The enteric polymers are claimed cellulose acetate phthalate and cellulose acetate trimellitate (Examples and claims 4 and 5).

One of ordinary skill in the art would be motivated to use Allemann et al's nanodispersions for the delivery of water insoluble drugs with a reasonable expectation of success since Kawata shows the feasibility of enteric delivery of water insoluble drugs using enteric formulations containing water insoluble drugs. One of ordinary skill in the art would be motivated to use the formulations of Allemann and containing water insoluble drugs orally since Igari and Kantor teach that suspensions of enterically coated nanocapsules can be administered orally. Although Allemann does not teach claimed enteric polymers such as hydroxypropylmethyl cellulose phthalate and cellulose acetate trimellitate, it would have been obvious to one of ordinary skill in the art to use these polymers, with a reasonable expectation of success since the references of Kawata and Kantor teach that these are enteric polymers which could be used for enteric coatings.

Art Unit: 1615

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant deletes methacrylic polymers taught by Allemann and argues that Allemann by itself does not render the amended claim obvious since Allemann does not disclose or teach the remaining polymers claimed in claim 1. This argument is not found to be persuasive. Although Allemann by itself may or may not render the claims obvious, since the secondary references of Kawata and Kantor show the use of methacrylic acid and methacrylic esters, hydroxypropylmethyl cellulose phthalates, cellulose acetate phthalate and cellulose acetate trimellitate are enteric polymers and are routinely used in the enteric coatings, one of ordinary skill in the art would be motivated to use any of the known enteric polymers with a reasonable expectation of success. Applicant once again argues that Allemann specifically refers to an injectable sustained release dosage form and that an injection is different from an oral dosage form. This argument is not persuasive. As pointed out in the previous action, instant claims are composition claims and intended use has no patentable significance and there is nothing in the reference, which precludes the administration of the nanospheres by oral administration. The very fact that one of the polymers taught by Allemann is Eudragit S is an enteric polymers implies that one can use the formulation by means other than injection since this polymer dissolves at pH 7 and upwards which is intestinal pH.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1615

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

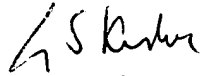
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK